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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,078	04/08/2004	Robert A. Davis	56630US007	1677

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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
07/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
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Office Action Summary	Application No.	Applicant(s)	
	10/821,078	DAVIS ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/10/09,7/1/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the Pre-appeal Conference Request filed on October 16, 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761

Information Disclosure Statements

2. The information disclosure statements (IDS) submitted on June 10, 2009 and July 1, 2009 were filed after the mailing date of the final action on July 16, 2008. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 78-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no iodine complex, chlorhexidine or chlorhexidine salt recited in either claim 58 or claim 73.

5. Claim 78 recites the limitation "the iodine complex" in line 2. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 79 recites the limitation "the chlorhexidine" in line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 80 recites the limitation "the chlorhexidine salt" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 58-60, 62-70, 72, 76, 77, 81, 83-89 and 91-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby et al (U.S. Patent Application Publication No. 2002/0076258) in view of Petterson et al (WO 99/03677 A1).

With respect to **claim 58:** Examiner is invoking 35 U.S.C. 112, sixth paragraph in the interpretation of claim 58, specifically with regard to the interpretation of the recited dispensing means. Crosby discloses a skin antiseptic composition dispenser 10 comprising the following: a container in the form of hollow handle 20 defining an interior volume, wherein the container comprises one or more polymeric walls free of metallic foil layers (¶0030); skin antiseptic composition located within the interior volume of the container (¶0029); and dispensing means in the form of ruptured portion 43 for dispensing the skin antiseptic composition (¶0032); wherein the container 20 is impermeable to liquid and vapor phases of the skin antiseptic composition inasmuch as Crosby discloses that the material of the handle must remain stable in the presence of the particular disinfectant solution contained therein (¶0030); and wherein the container further comprises at least one barrier layer made of polyethylene terephthalate (PET), a material identical to one disclosed by applicant as a material for the recited barrier layer and thus necessarily substantially impermeable to gaseous ethylene oxide. (¶0030)

Crosby discloses that the container is made of PET, which is inherently and necessarily substantially impermeable to ethylene oxide as the phrase "substantially impermeable" is defined in the disclosure. However Crosby does not disclose that the container is provided with a sterile exterior. Petterson discloses subjecting an article having a barrier laminate made of polyester (e.g. PET) which is impermeable to ethylene oxide and discloses subjecting that laminate's exterior to a sterilizing gas, i.e. ethylene oxide. Petterson discloses that the use of ethylene oxide as a sterilizing gas for medical articles is well known in the art. As the benefits of

sterilizing the exterior of such an article are self-explanatory, it would be obvious to one of ordinary skill in the art to modify the article of Crosby by providing the container with a sterile exterior as disclosed by Petterson with a reasonable expectation of success to prevent contamination of the article and composition therein prior to use.

With regard to the limitation "by exposure to a sterilizing gas" such limitation constitutes product by process claim language. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) Further, Petterson discloses creation of a sterile exterior by exposure to a sterilizing gas, thus the article of Crosby as modified by Petterson renders this limitation unpatentable.

With respect to **claim 59:** Crosby discloses that the entire container 20 is made from PET (¶0030) and thus does not disclose that the barrier layer covers less than 100% of one or more of the walls. However, it would be obvious to one of ordinary skill in the art to modify the article of Crosby such that the barrier layer covers lessthan 100%, specifically that it does not cover the top end, with a reasonable expectation of success as Crosby only requires that the material be stable in the presence of the disinfectant. Thus the barrier need only cover the area that equates to the maximum level of solution in the container.

With respect to **claim 60:** Crosby discloses that the entire container 20 is made from PET, thus the barrier layer necessarily covers at least 60% of one or more of the walls. (¶0030)

With respect to **claim 62:** The barrier layer disclosed by Crosby that is substantially impermeable to ethylene oxide comprises polyester, specifically PET. (¶0030)

With respect to **claim 63:** Crosby discloses that the one or more walls comprise a layer of polyolefin or PET. (¶0030)

With respect to **claim 64:** The dispenser disclosed by Crosby further comprises a dispensing seal in the form of rupturable membrane 41 comprising a seal layer attached over a dispensing orifice in the container 20.

With respect to **claim 65:** The container 20 disclosed by Crosby comprises a vent opening sealed by plug 21 into the interior volume of the container, wherein the vent is located remote from the dispensing orifice. (Fig. 2, ¶0030)

With respect to **claim 66:** The vent comprises a vent orifice and a vent seal in the form of plug 21 closing the vent orifice. (¶0030)

With respect to **claim 67:** The vent seal 21 disclosed by Crosby comprises a seal layer in the form of the flange portion of the plug resting over the orifice and attached to the container over

the vent orifice. (Fig. 2)

With respect to **claim 68:** The one or more walls free of metallic foil layers disclosed by Crosby are polymeric layers such as polyolefin which are by their nature flexible materials. (¶0030)

With respect to **claim 69:** The container 20 disclosed by Crosby is cylindrical. (Fig. 1)

With respect to **claim 70:** Crosby discloses that the layers are integral to container 20 and thus do not disclose that the layer that is substantially impermeable to ethylene oxide is a barrier layer adhered to at least a portion of the exterior of the container.

With respect to **claim 72:** Crosby discloses that the one or more walls comprise a layer of polyolefin or PET. (¶0030)

With respect to **claim 76:** Applicant discloses in the specification that the limitation of claim 76 is an attribute of the polymeric walls that are impermeable to the skin antiseptic composition as impermeability with respect to the composition is defined in the specification, i.e. that some components may still permeate. Thus, since Crosby anticipates the recited polymeric walls impermeable to skin antiseptic, the container, packaged as to be shipped, will inherently and necessarily lose 2% or less by weight of the skin antiseptic composition when placed in a convection oven at 60 degrees Celsius for 14 days.

With respect to **claim 77:** Crosby anticipates the recited polymeric walls impermeable to skin antiseptic and contains PET, a material identical to one disclosed by applicant as being

substantially impermeable to ethylene oxide. Further the limitation of claim 77 is one of the definitions of the phrase "substantially impermeable" disclosed by applicant. Thus the container of Crosby, packaged as to be shipped, will inherently exhibit permeability to gaseous ethylene oxide of 20 mg/hr/cm^2 or less. Therefore, though Crosby does not explicitly disclose a permeability to gaseous ethylene oxide, it would be obvious to one of ordinary skill in the art to modify the article of Crosby such that the container, packaged to be shipped, will exhibit a permeability to gaseous ethylene oxide within the claimed range with a reasonable expectation of success to permit sterilization of the container without risk of contamination of the skin composition therein.

With regard to the limitation "when determined in accordance with the Gaseous Ethylene Oxide Permeability Test", The test method recited in the claim *per se* does not substantially affect the value of a specific parameter, which is a characteristic of the material and depends on the structure and make up of a material, but not on the method of its determination. Since the test method does not essentially affect the compositional characteristics of the recited container during testing, the test method bears little patentable weight because any test method will yield substantially identical results, and thus the test method used cannot be the basis for patentability over the prior art.

With respect to **claim 81:** Examiner is invoking 35 U.S.C. 112, sixth paragraph in the interpretation of claim 58, specifically with regard to the interpretation of the recited dispensing means. Crosby discloses a skin antiseptic composition dispenser 10 comprising the following: a container in the form of hollow handle 20 defining an interior volume, wherein the container comprises one or more polymeric walls free of metallic foil layers (¶0030); skin antiseptic composition located within the interior volume of the container (¶0029); and dispensing means

in the form of ruptured portion 43 for dispensing the skin antiseptic composition (¶0032); wherein the container 20 is impermeable to liquid and vapor phases of the skin antiseptic composition inasmuch as Crosby discloses that the material of the handle must remain stable in the presence of the particular disinfectant solution contained therein (¶0030); and wherein the container further comprises at least one barrier layer made of polyethylene terephthalate (PET), a material identical to one disclosed by applicant as a material for the recited barrier layer and thus necessarily substantially impermeable to gaseous ethylene oxide. (¶0030)

Crosby discloses that the container is made of PET, which is inherently and necessarily substantially impermeable to ethylene oxide as the phrase "substantially impermeable" is defined in the disclosure. However Crosby does not disclose that the container is provided with a sterile exterior. Petterson discloses subjecting an article having a barrier laminate made of polyester (e.g. PET) which is impermeable to ethylene oxide and discloses subjecting that laminate's exterior to a sterilizing gas, i.e. ethylene oxide. Petterson discloses that the use of ethylene oxide as a sterilizing gas for medical articles is well known in the art. As the benefits of sterilizing the exterior of such an article are self-explanatory, it would be obvious to one of ordinary skill in the art to modify the article of Crosby by providing the container with a sterile exterior as disclosed by Petterson with a reasonable expectation of success to prevent contamination of the article and composition therein prior to use.

With regard to the limitation “by exposure to a sterilizing gas” such limitation constitutes product by process claim language. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence

establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) Further, Petterson discloses creation of a sterile exterior by exposure to a sterilizing gas, thus the article of Crosby as modified by Petterson renders this limitation unpatentable.

The container further comprises at least one barrier layer made of polyethylene terephthalate (PET), a material identical to one disclosed by applicant as a material for the recited barrier layer and thus necessarily substantially impermeable to gaseous ethylene oxide. (¶0030) As the limitation "permeability to gaseous ethylene oxide of 20 mg/hr/cm^2 or less" is one definition applicant discloses for the phrase "substantially impermeable" and Crosby discloses a material identical to one disclosed for the recited barrier layer, though Crosby does not explicitly disclose a permeability to gaseous ethylene oxide, it would be obvious to one of ordinary skill in the art to modify the article of Crosby such that the barrier layer meets this limitation with a reasonable expectation of success to ensure the composition is not impaired or contaminated by the sterilizing ethylene oxide gas.

With respect to **claim 83:** Crosby discloses one flexible wall free of metallic foil and thus does not disclose one or more flexible walls free of metallic foil layers comprise an inner layer facing the interior volume and an outer layer facing away from the interior volume. Petterson discloses a heat-sealed laminate of an outer-facing PET layer with another polyolefin layer. The outer layer is substantially impermeable to liquid and vapor phases of the skin antiseptic composition, inasmuch as it is identical to a material disclosed by applicant as being both impermeable to the liquid and gas phases of the recited skin composition and ethylene oxide sterilizing gas. With regard to the limitation "wherein at least one of the inner layer and the outer layer exhibits permeability to gaseous ethylene oxide of 20 lng/hr/cm^2 or less", whichever layer the PET layer

serves as will inherently exhibit such a permeability to gaseous ethylene oxide. As the limitation "permeability to gaseous ethylene oxide of 20 mg/hr/cm^2 or less" is one definition applicant discloses for the phrase "substantially impermeable" and both Crosby and Petterson disclose a material identical to one disclosed for the recited barrier layer, though neither does not explicitly disclose a permeability to gaseous ethylene oxide, it would be obvious to one of ordinary skill in the art to modify the article of Crosby as modified by Petterson having the one or more walls free of foil layers such that the barrier layer meets this limitation with a reasonable expectation of success to ensure the composition is not impaired or contaminated by the sterilizing ethylene oxide gas. ('677, Page 9, lines 19-21)

With respect to **claim 84:** Crosby does not disclose an outer layer and inner layer. Petterson discloses a laminate of three layers wherein the outer-facing layer comprises PET, a polyester. Since the article of Petterson seeks to solve a similar problem in the art to that with which applicant is concerned, it would be obvious to one of ordinary skill in the art to modify the article of Crosby such that the container comprises one or more layers free of metallic foil wherein the outer layer is made of polyester as disclosed by Petterson with a reasonable expectation of success to provide a barrier to sterilizing ethylene oxide gas to permit sterilization of the container without contamination of the skin composition. ('677, Page 9, lines 19-21)

With respect to **claim 85:** Crosby discloses only one layer and thus does not disclose an inner layer. The inner layer disclosed by Petterson is a layer of polyolefin, namely polypropylene. ('677, Page 9, lines 19-21) The motivation to modify the article of Crosby such that the container is made of the laminate disclosed by Petterson is stated *supra* with respect to claim 84.

With respect to **claim 86:** Crosby discloses that the dispenser 10 further comprises a dispensing seal in the form of rupturable portion 41 comprising a seal layer attached over a dispensing orifice in the container. ('258, ¶0032)

With respect to **claim 87:** The container 20 disclosed by Crosby comprises a vent opening sealed by plug 21 into the interior volume of the container, wherein the vent is located remote from the dispensing orifice. ('258, Fig. 2, ¶0030)

With respect to **claim 88:** The vent comprises a vent orifice and a vent seal in the form of plug 21 closing the vent orifice. ('258, ¶0030)

With respect to **claim 89:** Examiner is invoking 35 U.S.C. 112, sixth paragraph in the interpretation of claim 58, specifically with regard to the interpretation of the recited dispensing means. Crosby discloses a skin antiseptic composition dispenser 10 comprising the following: a container in the form of hollow handle 20 defining an interior volume, wherein the container comprises one or more polymeric walls free of metallic foil layers (¶0030); skin antiseptic composition located within the interior volume of the container (¶0029); and dispensing means in the form of ruptured portion 43 for dispensing the skin antiseptic composition (¶0032); wherein the container 20 is impermeable to liquid and vapor phases of the skin antiseptic composition inasmuch as Crosby discloses that the material of the handle must remain stable in the presence of the particular disinfectant solution contained therein (¶0030); and wherein the container further comprises at least one barrier layer made of polyethylene terephthalate (PET), a material identical to one disclosed by applicant as a material for the recited barrier layer and thus necessarily substantially impermeable to gaseous ethylene oxide. (¶0030)

Crosby discloses that the container is made of PET, which is inherently and necessarily substantially impermeable to ethylene oxide as the phrase "substantially impermeable" is defined in the disclosure. However Crosby does not disclose that the container is provided with a sterile exterior. Petterson discloses subjecting an article having a barrier laminate made of polyester (e.g. PET) which is impermeable to ethylene oxide and discloses subjecting that laminate's exterior to a sterilizing gas, i.e. ethylene oxide. Petterson discloses that the use of ethylene oxide as a sterilizing gas for medical articles is well known in the art. (‘677, Page 1, line 9, Page 9, lines 19-21), As the benefits of sterilizing the exterior of such an article are self-explanatory, it would be obvious to one of ordinary skill in the art to modify the article of Crosby by providing the container with a sterile exterior as disclosed by Petterson with a reasonable expectation of success to sterilize the article while preventing contamination of the article and composition therein prior to use.

With respect to **claim 91:** The outer layer disclosed by Crosby comprises polyester, namely PET. (¶0030)

With respect to **claim 92:** Crosby discloses only one layer and thus does not disclose an inner layer. The inner layer disclosed by Petterson is a layer of polyolefin, namely polypropylene. (‘677, Page 9, lines 19-21) Since the article of Petterson seeks to solve a similar problem in the art to that with which applicant is concerned, it would be obvious to one of ordinary skill in the art to modify the article of Crosby such that the container comprises one or more layers free of metallic foil wherein the outer layer is made of polyester as disclosed by Petterson with a reasonable expectation of success to provide a barrier to sterilizing ethylene oxide gas to permit sterilization of the container without contamination of the skin composition. (‘677, Page 9, lines

19-21)

With respect to **claim 93:** Crosby discloses that the dispenser 10 further comprises a dispensing seal in the form of rupturable portion 41 comprising a seal layer attached over a dispensing orifice in the container. ('258, ¶0032)

With respect to **claim 94:** The container 20 disclosed by Crosby comprises a vent opening sealed by plug 21 into the interior volume of the container, wherein the vent is located remote from the dispensing orifice. ('258, Fig. 2, ¶0030)

With respect to **claim 95:** The vent disclosed by Crosby comprises a vent orifice and a vent seal in the form of plug 21 closing the vent orifice. ('258, ¶0030)

With respect to **claim 96:** The vent seal 21 disclosed by Crosby comprises a seal layer in the form of the flange portion of the plug resting over the orifice and attached to the container over the vent orifice. ('258, Fig. 2)

12. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby ('258) in view of Petterson et al ('677) as applied to claim 58 above and further in view of Fendler et al (U.S. Patent No. 6,333,039).

With respect to **claim 61:** Crosby discloses an alcohol-based skin composition but does not explicitly disclose that the skin antiseptic composition comprises an agent selected from the group consisting of iodine, an iodine complex, chlorhexidine, triclosan, octenidine and

combinations thereof. Fendler discloses an opaque skin sanitizing composition that comprises alcohol and triclosan. Since the prior art of Fendler seeks to solve a similar problem in the art to that with which applicant is concerned (i.e. providing an effective skin antiseptic composition) it would be obvious to one of ordinary skill in the art to modify the article of Crosby such that the alcohol based skin composition comprises triclosan as disclosed by Fendler with a reasonable expectation of success to provide an effective skin antiseptic composition.

13. Claims 71 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby (‘258) in view of Petterson et al (‘677) as applied to claim 58 above and further in view of Langley (U.S. Patent No. 5,560,974).

With respect to **claim 71:** Crosby does not disclose a barrier layer that is adhered using a pressure sensitive adhesive, heat activated adhesive, or hot melt adhesive. Langley discloses a barrier laminate containing a layer of polyethylene terephthalate laminated via thermoplastic (i.e. hot melt) adhesive to another polyolefin layer, which may also be PET. Langley discloses that this laminate serves as a barrier to escape of biological fluids. Therefore since Langley discloses a material identical to one disclosed by applicant for the ethylene oxide barrier material, and the prior art of Langley seeks to solve a similar problem in the art to that with which applicant is concerned, it would be obvious to one of ordinary skill in the art to modify the article of Crosby such that the barrier layer is adhered to at least a portion of the container material layer via hot melt adhesive as disclosed by Langley with a reasonable expectation of success to provide a barrier to the skin disinfectant composition, bodily fluids and ethylene oxide sterilizing gas.

With respect to **claim 73:** Examiner is invoking 35 U.S.C. 112, sixth paragraph in the interpretation of claim 58, specifically with regard to the interpretation of the recited dispensing means. Crosby discloses a skin antiseptic composition dispenser 10 comprising the following: a container in the form of hollow handle 20 defining an interior volume, wherein the container comprises one or more polymeric walls free of metallic foil layers (¶0030); skin antiseptic composition located within the interior volume of the container (¶0029); and dispensing means in the form of ruptured portion 43 for dispensing the skin antiseptic composition (¶0032); wherein the container 20 is impermeable to liquid and vapor phases of the skin antiseptic composition inasmuch as Crosby discloses that the material of the handle must remain stable in the presence of the particular disinfectant solution contained therein (¶0030); and wherein the container further comprises at least one barrier layer made of polyethylene terephthalate (PET), a material identical to one disclosed by applicant as a material for the recited barrier layer and thus necessarily substantially impermeable to gaseous ethylene oxide. (¶0030)

Crosby discloses that the container is made of PET, which is inherently and necessarily substantially impermeable to ethylene oxide as the phrase "substantially impermeable" is defined in the disclosure. However Crosby does not disclose that the container is provided with a sterile exterior. Petterson discloses subjecting an article having a barrier laminate made of polyester (e.g. PET) which is impermeable to ethylene oxide and discloses subjecting that laminate's exterior to a sterilizing gas, i.e. ethylene oxide. Petterson discloses that the use of ethylene oxide as a sterilizing gas for medical articles is well known in the art. As the benefits of sterilizing the exterior of such an article are self-explanatory, it would be obvious to one of ordinary skill in the art to modify the article of Crosby by providing the container with a sterile exterior as disclosed by Petterson with a reasonable expectation of success to prevent contamination of the article and composition therein prior to use.

With regard to the limitation "by exposure to a sterilizing gas" such limitation constitutes product by process claim language. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) Further, Petterson discloses creation of a sterile exterior by exposure to a sterilizing gas, thus the article of Crosby as modified by Petterson renders this limitation unpatentable.

Crosby does not disclose a barrier layer that is adhered using a pressure sensitive adhesive, heat activated adhesive, or hot melt adhesive. Petterson discloses a heat-sealed laminate of a PET layer with another polyolefin layer, but discloses that this is accomplished by melting the two polyolefin layers together and does not disclose an adhesive. Langley discloses a barrier laminate containing a layer of polyethylene terephthalate laminated via thermoplastic (i.e. hot melt) adhesive to another polyolefin layer, which may also be PET. Langley discloses that this laminate serves as a barrier to ingress or escape of biological fluids. Therefore since Langley discloses a material identical to one disclosed by applicant for the ethylene oxide barrier material, and the prior art of Langley seeks to solve a similar problem in the art to that with which applicant is concerned, it would be obvious to one of ordinary skill in the art to modify the article of Crosby such that the barrier layer is adhered to at least a portion of the container material layer via hot melt adhesive as disclosed by Langley with a

reasonable expectation of success to provide a barrier to the skin disinfectant composition, bodily fluids and ethylene oxide sterilizing gas.

With respect to **claim 74:** The barrier layer of the article of Crosby as modified by Petterson and as further modified by Langley is made of PET, a material identical to one disclosed by applicant for the claimed barrier layer that is substantially impermeable to ethylene oxide. The motivation to modify the article of Crosby as modified by Petterson so as to have a barrier layer adhered to the exterior of the container as disclosed by Langley is stated *supra* with respect to claim 73.

With respect to **claim 75:** The barrier layer of the article of Crosby as modified by Petterson and as further modified by Langley comprises a layer selected from the group consisting of a layer of polyolefin. ('974, Col. 6, lines 25-37) The motivation to modify the article of Crosby as modified by Petterson so as to have a barrier layer adhered to the exterior of the container as disclosed by Langley is stated *supra* with respect to claim 73.

14. Claims 78, 79, 82 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby ('258) in view of Petterson et al ('677) as applied to claims 58 and 81 above, and further in view of Hoang et al (U.S. Patent No. 5,607,699).

With respect to **claim 78:** Crosby does not explicitly disclose that the skin composition contains an iodine complex that comprises an iodophor. Hoang discloses that iodophor iodine complexes as skin disinfectant agents are known in the art. As their benefit as disinfectant is self-explanatory it would be obvious to one of ordinary skill in the art to modify the article of Crosby as modified by Petterson such that the skin composition comprises an iodine complex that is an

iodophor with a reasonable expectation of success to impart disinfecting benefit to the user's skin.

With respect to **claim 79:** Crosby does not explicitly disclose that the skin composition comprises a chlorhexidine that is a chlorhexidine salt. Hoang discloses that chlorhexidine gluconate, a chlorhexidine salt, as a skin disinfectant agent is known in the art and is less irritating to the skin than other disinfectants. As the benefit of a disinfectant is self-explanatory and the chlorhexidine salt is less irritating to the skin, it would be obvious to one of ordinary skill in the art to modify the article of Crosby as modified by Petterson such that the skin composition comprises a chlorhexidine salt such as chlorhexidine gluconate as disclosed by Hoang with a reasonable expectation of success to impart disinfecting benefit to the user's skin.

With respect to **claims 82, 90:** Crosby does not explicitly disclose that the skin composition comprises an agent selected from the group consisting of iodine, an iodine complex, chlorhexidine, and combinations thereof. Hoang discloses that iodophor iodine complexes as skin disinfectant agents are known in the art. As their benefit as disinfectant is self-explanatory it would be obvious to one of ordinary skill in the art to modify the article of Crosby as modified by Petterson such that the skin composition comprises an iodine complex that is an iodophor with a reasonable expectation of success to impart disinfecting benefit to the user's skin.

15. Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby (‘258) in view of Petterson et al (‘677) as applied to claim 58 above, and further in view of Behrends et al (U.S. Patent Application Publication No. 2001/0036963).

With respect to **claim 80:** Crosby does not explicitly disclose that the skin composition comprises a chlorhexidine that is selected from the group consisting of chlorhexidine digluconate and chlorhexidine diacetate. Behrends discloses that the use of chlorhexidine digluconate in hand sanitizing and disinfecting compositions is well known in the art. ('963, ¶0003) As the benefit of a disinfectant is self-explanatory and the chlorhexidine salt is less irritating to the skin, it would be obvious to one of ordinary skill in the art to modify the article of Crosby as modified by Petterson such that the skin composition comprises a chlorhexidine salt such as chlorhexidine digluconate as disclosed by Behrends with a reasonable expectation of success to impart disinfecting benefit to the user's skin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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